

II. Rejection Under 35 U.S.C. § 112, second paragraph

Claims 18-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Insofar as it may be applied to the present claims, this rejection is respectfully traversed.

Claims 18 and 19 were said to be indefinite because it was unclear what saccharides are considered “essential saccharides.” Paragraph [0058] of the specification has been amended to provide a definition of essential saccharides from International Patent Application Publication Number WO 98/06418, the disclosure of which was incorporated into this application. A copy of International Patent Application Publication No. WO 98/06418 is submitted herewith for the convenience of the Examiner.

Claim 20 has been amended to delete recitation of the term “bioregulation of trauma stress.” Claim 24 has been amended to delete recitation of the term “toxin-related activities.”

In light of the foregoing amendments, Applicant submits that the rejection of claims 18-24 under 35 U.S.C. § 112, second paragraph has been overcome and therefore requests that it be withdrawn.

III. Rejections Under 35 U.S.C. § 102

Claims 5-7, 20, 22 and 24-27 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,241,983 to Paul et al. (hereafter referred to as “Paul ‘983”). Insofar as this rejection may be applied to the present claims, it is respectfully traversed.

As noted above, claims 5-7, 22 and 25-27 have been cancelled. In addition, claim 20 has been amended to specify a dietary supplement composition that includes a nutritionally effective amount of β -glucan, colostrum, lactoferrin and citrus pectin. Claim 24 has been amended to depend from and therefore includes the subject matter of claim 20.

As set forth in Manual of Patent Examining Procedure ("MPEP") § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Also, according to MPEP § 2131, to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim".

As noted above, claims 20 and 24 require a dietary supplement composition that includes a nutritionally effective amount of β -glucan, colostrum, lactoferrin and citrus pectin.

Paul '983 discloses a dietary supplement composition that includes human intestinal microorganisms and dietary fiber. See column 3 line 62 to column 4 line 1. Paul '983 discloses that the dietary fiber may include pectins (column 7, lines 52-53) and beta-glucans (column 9, lines 27-28). Paul '983 also discloses that the composition may include lactoferrin as an inhibitor of iron-catalyzed processes. Paul '983, however, does not disclose or suggest a composition that includes a nutritionally effective amount of β -glucan, colostrum, lactoferrin and citrus pectin. Accordingly, it is respectfully requested that the rejection of claims 20 and 24 under 35 U.S.C. §102(e) over Paul '983 be withdrawn.

Claims 7 and 27 stand rejected under 35 U.S.C. §102(b) as anticipated by (a) U.S. Patent No. 5,024,996 to Ringe (hereafter referred to as "Ringe '996") and (b) U.S. Patent No. 3,947,604 to McGinley et al. (hereafter referred to as "McGinley '604"). Insofar as these rejections may be applied to the present claims, they are respectfully traversed.

As noted above, claims 7 and 27 have been cancelled. Therefore, it is respectfully submitted that these rejections are moot and should be withdrawn.

IV. Rejection Under 35 U.S.C. § 103(a)

Claims 1-4 and 8-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,576,015 to Donzis (hereafter referred to as "Donzis '015"), U.S. Patent No. 5,531,989 to Paul (hereafter referred to as "Paul '989") and International Publication No. WO 97/05884 to Plaut (hereafter referred to as "Plaut '884"). As noted above, claims 2-7, 21-23 and 25-27 have been cancelled. Insofar as this rejection may be applied against claims 1, 8-20 and 24, it is respectfully traversed.

Each of claims 1, 8-20 and 24 pertain to a dietary supplement composition that includes a nutritionally effective amount of β -glucan, colostrum, lactoferrin and citrus pectin.

Donzis '015 discloses the use of beta (1,3) yeast extract glucan particles as nutritional supplements.

Paul '989 discloses an immunoglobulin and fiber-containing composition for use as a dietary supplement for restoring and maintaining gastrointestinal health. Paul '989 discloses that the fiber portion of the dietary supplement may include pectin and fructo-oligosaccharides. Paul '989 also discloses that the dietary supplement may optionally include lactoferrin as an inhibitor of detrimental iron-catalyzed processes. Paul '989 discloses that:

[w]hile prior art formulas as dietary supplements containing soluble dietary fiber or immunoglobulins are known and are generally suitable for their limited purposes, they possess certain inherent deficiencies that detract from their overall utility in restoring and maintaining gastrointestinal health. For example, a dietary supplement containing soluble dietary fiber without concentrated immunoglobulins lacks means for binding and inactivating foreign antigens such as pathogenic bacteria, viruses, fungi, and protozoa that can infect the gastrointestinal tract and are detrimental to the health thereof.

Thus, Paul '989 discloses that the dietary supplement for restoring and maintaining gastrointestinal health must include concentrated immunoglobulins and soluble dietary fiber.

Plaut '884 discloses an infant formula which includes pasteurized milk, active lactoferrin, and an antibody which specifically binds at least one of an IgA protease and an IgA protease precursor.

Accordingly, none of Donzis '015, Paul '989 or Plaut '884 taken alone disclose or suggest the subject matter of claims 1, 8-20 and 24.

According to MPEP § 2142, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. Beyond this, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art rather than the applicant's disclosure.

Additionally, as noted in MPEP § 2143.01, just because references can be combined does not render a combination obvious, unless the prior art also suggests the desirability of the combination. As noted in *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998), there must be evidence that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. Moreover, as noted in *Rouffet*, a rejection cannot be predicated on the mere identification of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. Here, no such evidence has been presented. And there is absolutely no teaching, suggestion or motivation to support the combination of the references put forth by the Examiner.

Furthermore, as noted in MPEP § 2142, hindsight, after disclosure of the applicant's invention, may not be used to conclude that the invention is obvious. It is respectfully submitted that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. As the Federal Circuit stated in *In re Kotzah*, 217 F.3d 1365, 1370 (Fed. Cir. 2000), "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability." It is respectfully submitted that the only way the references cited by the Examiner could be pieced together to defeat patentability is indeed to use Applicant's disclosure of the four component composition as a blueprint. Therefore, the combination of references is improper.

In addition, even if there was a motivation or suggestion to combine Donzis '015, Paul '989 and Plaut '884, the resulting composition would include beta (1,3) yeast extract glucan particles according to Donzis '015, concentrated immunoglobulins and soluble dietary fiber according to Paul '989 and pasteurized milk, active lactoferrin, and an antibody which specifically binds at least one of an IgA protease or an IgA protease precursor according to Plaut '884. Thus, even if it were proper to combine the disclosures of Donzis '015, Paul '989 and Plaut '884, the result would not be the dietary supplement of claims 1, 8-20 and 24.

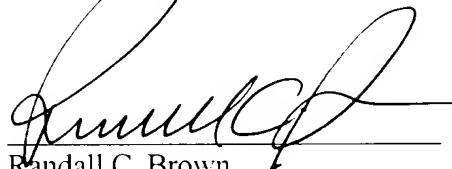
Accordingly, for the foregoing reasons, it is respectfully submitted that none of Donzis '015, Paul '989 and Plaut '884 disclose or suggest the subject matter of claims 1, 8-20 and 24. Moreover, it is respectfully submitted that it is improper to combine any of such references since there is no motivation or suggestion for such combination to achieve the applicant's claimed dietary supplement, and even if there were, the result would not be the dietary supplement of claims 1, 8-20 and 24.

Therefore, for all of the foregoing reasons, it is requested that the rejection of claims 1-4 and 8-26 under 35 U.S.C. §103(a) over the combination of Donzis '015, Paul '989 and Plaut '884, be withdrawn.

V. Conclusion

It is believed that all matters set forth in the Office Action have been addressed. Applicant has made a diligent effort to advance the prosecution of this application by amending claims 1, 9, 10, 12, 16, 18, 20 and 24 and by submitting arguments in support of the patentability of claims 1, 8-20 and 24. In light of the foregoing amendment and remarks, Applicant submits that Claims 1, 8-20 and 24 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited.

Respectfully submitted,



Randall C. Brown
Registration No. 31,213

Date: 8/30/02
HAYNES AND BOONE, LLP
901 Main Street - Suite 3100
Dallas, Texas 75202-3789
Telephone: 214/651-5242
Facsimile: 214/200-0802
File: 23100.40
1053651v1

**ATTACHMENT A: MARKED UP VERSION OF AMENDMENTS
TO THE SPECIFICATION AND THE CLAIMS**

In the Specification:

Paragraph [0058], beginning on page 16, line 15, and ending at page 16, line 25, is amended as indicated below.

[0058] The components of the compositions of the present invention help trigger a cascade of immune signaling mechanisms. This is especially important when stress factors work against the immune system. Glyconutrients help carry these immune signals to other cells. According to a preferred embodiment, the compositions of the present invention are combined with a complex of essential saccharides such as the dietary supplement sold by Mannatech Inc. of Coppell, Texas under the trade name "Ambrotose®." The Ambrotose® product is preferably produced according to the methods and procedures set forth in International Patent Application Publication Number WO 98/06418, the entire disclosure of which is hereby incorporated by reference herein. As noted in International Patent Application Publication Number WO 98/06418, the essential saccharides include galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, xylose, arabinose, glucuronic acid, galacturonic acid, iduronic acid, arabinogalactan, acetylated mannose, glucosamine and galactosamine. The combination of the compositions of the present invention and Ambrotose® complex provide a synergistic array of proteins, peptides, polypeptides, and glyco-proteins-nutrients that can help to achieve optimal health through an appropriately immunomodulated immune system.

In the Claims:

1. (Amended) A dietary supplement composition for a mammal, comprising a nutritionally effective amount of β -glucan, [and] colostrum, lactoferrin and citrus pectin.
9. (Amended) The dietary supplement composition of claim 1 [4] wherein said composition comprises from about 5 to about 83.3 weight percent of said colostrum, from about 0.909 to about 6.67 weight percent of said lactoferrin, from about 0.1 to about 1.25 weight percent of said citrus pectin, and from about 0.001 to about 10 weight percent of said β -glucan.
10. (Amended) The dietary supplement composition of claim 1 [4] further comprising a nutritionally effective amount of citric acid.
12. (Amended) The dietary supplement composition of claim 1 [4] further comprising a nutritionally effective amount of citric acid, dextrose, magnesium stearate, silicon dioxide and stearic acid.
16. (Amended) The dietary supplement composition of claim 1 [4] wherein said composition is prepared in a chewable delivery system.
18. (Amended) The dietary supplement composition of claim 1 [4] further comprising a complex of essential saccharides.
20. (Amended) A dietary supplement composition for producing in a mammal a first effect selected from the group consisting of regulation of the immune system, regulation of cytokine release, prevention of autoimmune response from intestinal pathogens, promotion of phagocytosis by neutrophils, stimulation of B cell and antibody secretion, inhibition of mast cell enzyme involved in allergic airway response, enhancement of natural killer cell activity,

stimulation of muscle protein synthesis, inhibition of muscle protein breakdown, stimulation of wound healing, stimulation of tissue repair, induction of cartilage formation and bone repair, anti-inflammatory effects, [bioregulation during trauma stress,] enhancement of hematopoietic activity, increase in insulin-like growth factor in tissues, antidiarrheal effect on gastrointestinal tract infection, stimulation of gastrointestinal tract growth, improvement in function of the gastrointestinal tract, promotion of the growth of beneficial gastrointestinal bacteria, lowering blood cholesterol, improving glucose tolerance, reducing average blood glucose in non-insulin-dependent diabetics, stimulation of glucose uptake by muscles, inhibition of the binding of bacteria to a host tissue, inhibition of the growth of bacteria, protection against viruses, enhancing activity of antibiotics, antifungal effects, anti-amoebic effects, prevention of tumor development, inhibition of tumor cell growth, inhibition of tumor metastasis, enhancement of natural killer cell toxicity to tumors, improvement in Alzheimer's dementia, antioxidant effects, and reaction against bacterial toxins, said dietary supplement composition comprising a nutritionally effective amount of β -glucan, [and at least one member selected from the group consisting of] colostrum, [and] lactoferrin and citrus pectin.

24. (Amended) The dietary supplement composition of claim 20 [22], said dietary supplement composition producing in a mammal a second effect selected from the group consisting of enhancing bile acid excretion, enhancing cholesterol excretion, reducing atherosclerosis [artherosclerosis], binding heavy metals, stimulation of immune function, resistance to infection, suppression of infection, increase of tissue repair and healing, promotion of body health and athletic performance, promotion of gastrointestinal tract health, promotion of blood vessel health, promotion of glucose utilization and blood sugar balance, improved cancer inhibition[,] and improved mental function[, and improved toxin-related activities].